

CLAIMS:

1. A method for detecting cancer cells, if present, in a tissue sample from a human patient, the method comprising contacting a tissue sample from a patient with a recognition agent for human cytochrome P450 CYP1B1, and detecting binding of the recognition agent to CYP1B1 protein in the prepared sample as an indication of the presence of cancer cells in the tissue sample.

10 2. A method according to claim 1 which includes the steps of obtaining from a patient a tissue sample to be tested for the presence of cancer cells; and producing a prepared sample in a sample preparation process; prior to contacting the prepared sample with a recognition agent that reacts with human CYP1B1 protein.

15 3. The method of claim 2 wherein binding of said recognition agent to CYP1B1 protein in sample is detected by immunohistochemical analysis.

20 4. The method of claim 3, wherein the sample preparation process comprises contacting the tissue with fixative and producing a thin section suitable for immunohistochemical analysis.

25 5. The method of claim 4, wherein the fixative is formalin.

30 6. The method of claim 4 or claim 5, wherein the thin section is wax-embedded.

35 7. The method of any one of claims 3 to 6, wherein the immunohistochemical analysis comprises a conjugated enzyme labelling technique.

8. The method of claim 2, wherein the sample preparation

process comprises tissue homogenization.

9. The method of claim 8, wherein the sample preparation process further comprises isolating microsomes.

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10 10. The method of claim 8 or claim 9, wherein the binding of said recognition agent to the CYP1B1 protein in the prepared sample is detected by Western blot analysis.

10 11. The method of claim 10, wherein the Western blot analysis comprises a conjugated enzyme labelling technique.

15 12. The method of claim 8, wherein the binding of said recognition agent to the CYP1B1 protein in the prepared sample is detected by an immunoassay.

13. The method of claim 12, wherein the immunoassay is selected from antibody capture assay, two-antibody sandwich assay and antigen capture assay.

20 14. The method of claim 12, wherein the immunoassay is a solid support-based immunoassay.

25 15. The method of any one of claims 12-14, wherein the immunoassay comprises a conjugated enzyme labelling technique.

16. The method of any one of the preceding claims, wherein the recognition agent is a polyclonal antibody.

30 17. The method of any one of claims 1 to 15, wherein the recognition agent is a monoclonal antibody.

35 18. The method of any one of the preceding claims, wherein the recognition agent recognizes a preselected epitope of the CYP1B1 protein.

19. The method of any one of claims 1 to 17, wherein the recognition agent is specific for CYP1B1 protein.

5 20. The method of any one of the preceding claims, wherein said tissue sample is selected from bladder, brain, breast, colon, connective tissue, kidney, lung, lymph node, oesophagus, ovary, skin, stomach, testis, and uterus.

10 21. A method of obtaining drugs of potential use in cancer therapy, which comprises screening for or selecting a substance which is susceptible to specific metabolism by human cytochrome P450 CYP1B1, and using that substance as a basis for a non-toxic moiety which can be converted by the CYP1B1 metabolism into a toxic one, which kills or 15 inhibits a tumour cell expressing CYP1B1 or makes it more susceptible to other agents.

20 22. A method of providing for the targeting of cytotoxic drugs or other therapeutic agents, or the targeting of imaging agents, in tumour diagnosis or therapy, which comprises providing the drug, therapeutic agent or imaging agent with means for the recognition of a human cytochrome P450 CYP1B1 epitope on the surface of a tumour cell, whether as part of the complete CYP1B1 protein itself or in some degraded form such as in the presentation on the surface of a cell bound to a MHC protein.

25 23. Use of a biologically active substance which is capable of stimulation of the human immune system by activating cytotoxic or helper T-cells which recognise human cytochrome P450 CYP1B1 epitopes in the preparation of a medicament to implement a cell-mediated or humoral immune response against a cell in which CYP1B1 is expressed.

30 24. The use of a biologically active substance according to claim 23, which activates the immune system by immunisation with at least one CYP1B1 amino acid sequence.

25. Use of a substance in the reduction of human cytochrome P450 CYP1B1 levels in tumour cells in the preparation of a medicament, wherein said substance comprising an inhibitor or means for producing antisense RNA to decrease the synthesis of CYP1B1.

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26. The use of a substance according to claim 25, which functions by down-regulation of the CYP1B1 promoter.

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